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Dear Mr. Vornberg:

This is in response to your letter of May 13, 2002, which provided the Missouri Department of Health and Senior Services (MDHSS) with a copy of The Doe Run Company's *Haul Road Risk Assessment for Herculaneum, Missouri.* Although the document lacks key supporting information, which prevents us from replicating the reported results, we have reviewed the assessment and offer our evaluation below.

As an introduction for community members who will read this letter and may be unfamiliar with the practice of risk assessment, we think it is important to provide some background on the subject. Above all, it is essential to understand that risk assessments are usually conducted using models. These models are simplified mathematical formulas that attempt to simulate science's current understanding of complex biological and physical processes. Lead risk assessment models combine information on people's potential exposures and lead toxicity to predict what is likely to happen to those who may be exposed.

Because a model is a mathematical calculation, it can only provide an estimate of risk. Models do not produce an irrefutable statement of fact. MDHSS relies on models that have been reviewed and approved by the U. S. Environmental Protection Agency (EPA). Also, we require that modelers use assumptions about typical human exposures and contaminant toxicity that have been approved by EPA. This is important to note because a modeler can change certain elements of the formula, producing dramatic differences in the results. Thus, the validity of a risk assessment is highly dependent on choices made by the modeler -- the choice of the model itself, the contaminant sampling plan, the assumptions about exposure, and the interpretation of the results. It stands to reason that mathematical models cannot realistically imitate natural processes if the inputs carry with them a high degree of uncertainty.

The Doe Run Company Haul Road Risk Assessment (HRRA) uses three models to predict blood lead concentrations that may result from children's and adult's exposures to haul route lead dust. Two of these models, the Integrated Exposure Uptake Biokinetic model (IEUBK) and the Adult Lead Model (ALM) are EPA approved models. In fact, these are the same models that MDHSS uses to assess lead contamination at mining and industrial sites in

Missouri. The model used in the HRRA to represent a child's exposure to a hot-spot area of lead concentrate, however, is not an EPA approved model.

The majority of MDHSS' reservations about the validity of this assessment – which follow – relate to three key areas of uncertainty:

- Use of unapproved toxicity and exposure assumptions,
- Modifications to an EPA model that have not been validated. and
- Use of an unapproved lead exposure model.

Our specific concerns are detailed below.

TOXICITY AND EXPOSURE ASSUMPTIONS

Bioavailability of Lead

A number of MDHSS' concerns with the validity of the risk assessment relate to assumptions made about the bioavailability of lead along the haul routes. We must seriously question the assumption that a lead ore concentrate sample taken directly from the mill is a reliable substitute for actual samples of lead dust from haul routes in Herculaneum. Further, this assumption fails to account for lead ore concentrate dust that is transported by the forces of wind and precipitation from the haul route source area to other exposure locations. Even if all other elements of the assessment are correct, MDHSS believes the results must be re-interpreted as characterizing only risks from exposure to lead ore concentrate at the four mills that supply the Doe Run smelter, and should not be extrapolated to exposures on and adjacent to haul route streets.

Secondly, MDHSS also holds concerns over whether an *In Vitro* bioassay accurately simulates lead uptake processes in children. EPA guidance (*IEUBK Model Bioavailability Variable*, [EPA #540-F-00-006, OSWER #9285.7-32], October 1999) warns that a number of factors, including a child's nutritional status and the time of ingestion of lead relative to meal times, can affect the uptake or absorption of ingested lead. This uncertainty was not discussed in the risk assessment. Further, according to a recommendation of EPA's Technical Review Workgroup for Lead (TRW), provisions of the 1995 Administrative Reform for Lead require a review of data that are substituted for default assumptions that may set a precedent. The TRW recommends that bioavailability data used in the IEUBK (other than those from published studies using the juvenile swine model) should be reviewed by EPA's Office of Emergency and Remedial Response.

In addition, MDHSS notes that the *In Vitro* bioassay was conducted on one composite sample and a duplicate. This limited analysis provides only a snapshot in time of the lead ore concentrate composition deposited along the haul routes. The lack of multiple samples does not provide any measure of the level of variation in ore composition that undoubtedly occurs in day-to-day mining and concentration operations. In addition, the laboratory report does not detail whether the materials in the composite sample were wholly and uniformly reduced to a <250 μg size, ensuring that rock/slag from the mill samples was not overly represented in the analyzed material.

Finally, MDHSS believes the risk assessment authors should have disclosed that the bioavailability of lead is a pivotal variable in this assessment. As stated above, models cannot reasonably imitate natural processes if the inputs carry with them a high degree of uncertainty. Given that the HRRA assumes a bioavailability of lead that is thirty times less than EPA's default assumption, and five times less than controlled studies of lead sulfide bioavailability reported in scientific literature, it would have been more informative to carry out multiple model runs with alternate bioavailability assumptions. A comparative risk assessment of this nature would give the citizens of the community and environmental management agencies a better understanding of the uncertainties associated with this key variable.

Dust Ingestion Rate

The assumption that 10% of the total daily intake of soil/dust is accidentally (incidentally) ingested during the daily walk by the child is an untested assumption. The risk assessment provides a detailed rationale for this assumption based on street dust loadings, however, this methodology does not appear in IEUBK guidance documents. As with the bioavailability estimate discussed above, MDHSS believes the Office of Emergency and Remedial Response should have reviewed this modification to the default estimate (as suggested in the EPA guidance document *IEUBK Model Soil/Dust Ingestion Rates, [EPA 540-F-00-007, OSWER 9285.7-33, Guidance Document], December 1999*).

MODIFICATIONS TO THE IEUBK MODEL

The HRRA calculates a "predicted incremental increase" in the blood lead level for a child with limited daily exposure to lead contaminated street dust. This is a non-standard approach to the IEUBK model, as it does not use the child's residence as the location of exposure. This method is not described in EPA guidance, and should probably be reviewed by the TRW. This methodology may provide a theoretical understanding of possible health impacts resulting from a child's daily walk along the haul routes in Herculaneum. However, MDHSS strongly urges citizens of the community to continue to act with caution along haul routes, as it is likely that children and adults also are being exposed to other sources of lead every day.

Modification of this model fundamentally alters the understanding that a child's home and surrounding yard is the basic unit for lead risk analysis, and eliminates the first two words in the model's title: *integrated* and *exposure*. MDHSS respectfully suggests that a truly objective, reasonable approach to assessing the impact of lead road dust on a population already at risk is to *integrate* site-specific environmental samples of soil, water, food, and air samples collected in Herculaneum, running the model with and without the street dust included as a fraction of the total soil ingestion.

USE OF AN UNAPPROVED LEAD EXPOSURE MODEL

The EPA has not accepted the model used to predict children's short-term exposure to a lead hot spot. As with the modification to the IEUBK model described above, MDHSS considers the one-time hot-spot exposure to a 2-½ year old child as completely theoretical, and not reflective of real children's activities. Indeed, it could be argued that young children might

be particularly attracted to hot-spot deposits of lead ore concentrate, as the texture resembles the sand in backyard, playground and day care center sandboxes. In addition, we could find no rationale on why the authors chose a total soil/dust ingestion rate of 100 mg/day rather than the default value used in the IEUBK model.

In conclusion, MDHSS must disagree that the HRRA is an objective risk assessment. We still don't know the risk of exposure to lead ore concentrate nor the total risk to children in the community whose blood lead levels may already be elevated due to exposures to multiple sources of lead. The document analyzes only one set of intake and bioavailability assumptions, and contains little discussion of the impact of variability and uncertainty in the data that was substituted for EPA's default assumptions. The measurements and modeling fail to account for lead dust that is transported by the forces of wind and precipitation from the haul route source area to other exposure locations, such as yards and homes. Further, we suggest this assessment should have included a sensitivity analysis – a specialized examination of the input parameters that discloses the impact of key assumptions on the results and conclusions of the analysis.

There are a number of additional minor issues with the risk assessment that are not detailed here. We would be glad to discuss these with you and the assessment's authors at a later time. Thank you for this opportunity to provide you with our concerns.

Sincerely,

Pamela Walker, Director
Division of Environmental Health
and Communicable Disease Prevention

cc: Dennis Diehl, Jefferson County Health Department
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